Remarks

Claims 1-10, 12, and 32-37 are pending in the present application.

The Examiner has objected to the abstract. An amended abstract is submitted herewith that has less than 150 words. No new matter is added by virtue of the amendments to the abstract. Accordingly, withdrawal of the objection is respectfully requested.

The Examiner's statement that claim 33 would be allowable if rewritten in independent form including the limitations of the base claim and any intervening claims is acknowledged. Claim 33 has been amended accordingly. Allowance of claim 33 is requested.

Claims 2-5, 12, 32, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection is respectfully traversed. It is submitted that the rejection fails to meet the fifth element of prima facie nonenablement as it relates to each of the below listed elements. Specifically, the rejection fails to demonstrate that the claimed invention requires undue experimentation since multiple dominant factors related to the showing of undue experimentation have not been met. Such elements will be addressed separately below:

1. The proffer that "E" is non-enabled value due to R_{KH} not being enabled (claim 2) is respectfully traversed.

It is submitted that while the specification discloses an example where "E" includes the factor "R_{KH}", the factor "E" itself is not dependent upon R_{KH} for its enablement. Rather, the factor "E" is an empirical factor (page 12 line 24) for a specific individual that relates to the anticipated rise in glucose concentration due to the consumption of carbohydrates. In this regard, the Examiner's attention is directed to page 11 lines 14-19 of the specification where it teaches that the factor "E" relates to the proportionality of the increase in the actual glucose value to the effective carbohydrate units in a projection period.

A single fixed value for this factor "E" is impractical because of the size difference in individuals with diabetes. For example, to convert from a mass of carbohydrates (g) to a concentration of glucose, one theoretically requires the volume in which glucose can be distributed and an equilibrium among different glucose compartments (blood, intercellular fluid, interstitial fluid). Undue experimentation is not, however, necessary to determine an "E" factor for various individuals for at least two reasons:

a. Both the actual glucose values and effective carbohydrate units can be obtained without undue experimentation. Actual glucose values can be measured from a patient and an example of the portion of effective carbohydrates is shown as the area described as A2-A1 in Figure 3. In light of the above, it is submitted that to derive the proportionality factor "E" from these easily determinable values would not require undue experimentation and is rather predictable.

b. Reasonable assumptions for such an "E" factor were well established in clinical practice literature before the filing date of the present application. Once such implementation of an assumption for the factor "E" is in US units. In this regard, the Examiner's attention is directed to page 124 lines 4-5 of Walsh, et al. "Stop the Rollercoaster, How to Take Charge of Your Blood Sugars in Diabetes", 1996, which is submitted herewith in a Supplemental Information Disclosure Statement. Walsh et al. teach, "A good rule of thumb is that 1 gram of glucose raises the blood sugar 3, 4, or 5 points (for weights of 200 lb., 150 lb., and 100 lb., respectively). A 5 gram glucose tablet should raise the blood sugar between 15 and 25 points, depending on your weight and activity."

Therefore, it is submitted that assumptions for a factor that relates to a proportionality of the increase in the actual glucose value to the effective carbohydrate units in a projection period was well known prior to the filing date of the application. Applicants have named that known proportionality factor "E".

As such, it is submitted that a factor "E" was known to those skilled in the art prior to the filing of the present application and is by definition derived from observation or experiment of an individual patient. Further, as disclosed in Walsh et al., "E", is rather predictable.

The specification is not required to teach every detail of the invention or to be a production specification. It need only explain how to make and use the invention without requiring an inordinate amount of experimentation. Accordingly, based on the guidance in the form of describing the factor E, in the form specific equations set forth in the specification, as well as the working example as discussed in the Reply filed January 30, 2003, it is submitted that undue experimentation would not be necessary to determine a value of E. Accordingly, the term "E" is believed to be enabled in accordance with 35 U.S.C. 112, first paragraph. Claims 3-5, 32, 34, and 35 depend from claim 2.

2. The rejection proffers that sufficient guidance in generating the "R_{KH}" value is not provided (claim 3). That rejection is respectfully traversed. R_{KH} is defined in the specification as a carbohydrate reduction factor that is used to reduce the effect of carbohydrates on blood glucose concentration. (page 11 lines 17-19).

It is submitted that values for R_{KH} could be determined without undue experimentation. For example, R_{KH} could be assessed (backwards from E) from an assumption (as discussed above). Note that the specification provides guidance as to R_{KH} at page 11, line 17 where the factor "E" is chosen as $R_{KH}(F)$. Claim 3 has been amended to recite that F is 0.25 mmol/l/g. As such, R_{KH} is readily determinable.

The specification is not required to teach every detail of the invention or to be a production specification. It need only explain how to make and use the invention without requiring an inordinate amount of experimentation. Therefore, based upon guidance provided in the specification, it is submitted that undue experimentation would not be necessary to determine a value for the term R_{KH}. The test of enablement is not whether experimentation is necessary, but if experimentation is undue. Here, the experimentation necessary to determine a value of a carbohydrate reduction factor is straightforward and predictable. Accordingly, the term R_{KH} is believed to be enabled in accordance with 35 U.S.C. 112, first paragraph.

3. The rejection proffers that the value determination of the empirical factor F is not enabled (claim 3). This proffer is respectfully traversed. Claim 3 has been amended to recite that the factor "F" is 0.25 mmol/l/g. Support is found in the specification at page 11 line 17. Accordingly, the term F is believed to be enabled in accordance with 35 U.S.C. 112, first paragraph.

4. The rejection proffers that the value of *m* of the summation lacks any definition and thus is not enabled (claim 12). That proffer is respectfully traversed. It is acknowledged that the term *m* is not explicitly defined in the specification. However, it is submitted that from the context of the specification the meaning of *m* is clear to one of ordinary skill in the art. Specifically, the term *m* is the number of carbohydrate consumptions to be considered.

First, direction and guidance as to determination of a value for *m* is set forth at page 8 by formula 4. It is described that the factor "KH_j" takes into account the consumption of carbohydrates at numerous points in time as well as a quantity of carbohydrate units consumed each time. Further, the formula indicates that the summation is made from j=1 to m and the description below formula 4 reciting that "the consumption of carbohydrates at numerous points in time" is considered, explains to the artisan which summation factors are taken into account. It is therefore reasonable to infer that "m" is an integer referring to the last consumption of carbohydrate that is taken into account as this way of indicating a summation of summation factors.

It is further submitted that a skilled artesian would make such an assumption based upon a comparison of originally filed claims 11 and 12. Claims 11 and 12 have an exactly matching structure (all "I"'s in claim 11 become "KH"'s in claim 12, the counter "i" in claim 11 becomes the counter "j" in claim 12, and "n" in claim 11 becomes "m" in claim 12). In claim 11 "n" is explicitly defined as the number of insulin doses to be considered. From this analogy, it is inferred that *m* is the number of the carbohydrate consumptions to be considered.

As such, it is submitted that the meaning of *m* would be clear to the artisan and that sufficient guidance and direction as to the determination of a value for *m* is provided to one skilled in the art. Accordingly, *m* is believed to be enabled in accordance with 35 U.S.C. 112, first paragraph.

In light of the above, reconsideration of the rejections, leading to withdrawal of the rejection and allowance of claims 2-5, 12, 32, 34, and 35 is respectfully requested.

Claims 5 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 5 and 32 have each been amended to recite that X is equal to SG(A). Support is found at page 11 lines 26-27. No new matter is added by virtue of the

amendment. The claims as amended are believed to be sufficiently definite for purposes of 35 U.S.C. 112, second paragraph. As such, reconsideration of the rejection leading to its withdrawal and allowance of the claims is respectfully requested.

Claims 1, 6-10, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worthington et al. taken with Goldman et al. (US 5,542,420A) in view of Conn et al. (WO 00/47109; 2000). It is submitted that the combination of the cited references fails to show or suggest the invention of independent claim 1. Claims 6-10 and 36-37 depend from claim 1.

Claim 1 has been amended to clarify that the system comprises an evaluation device that is formed for evaluating the data stored in the memory unit and based upon that stored data, for extrapolating a glucose concentration at a point in time (t_p). Support for the amendment is found in the specification at page 1 first paragraph and page 5 third paragraph and the claim as originally filed. No new matter is added by virtue of the amendment.

An important component of the presently claimed system is an evaluation unit, which performs an extrapolation for determining future glucose concentration. The extrapolation includes the determination of the portion of insulin dose that will become effective in the interval between measurement and the extrapolated point in time, and the determination of the portion of the carbohydrates that takes effect in this time interval. In accordance with the invention it was found that these two parameters are important, and that taking them into account leads to an extrapolated glucose concentration that allows for a sufficiently exact determination of a future glucose concentrations. (Page 5 third paragraph of the specification)

It is submitted that the cited art when considered as a whole fails to provide reason, suggestion, or motivation for a person of ordinary skill to have combined or modified the references to meet the limitations of claim 1. Specifically, it is submitted that Worthington et al. teach away from the claimed system.

Worthington et al. fails to recognize the importance of considering the portion of carbohydrates consumed when determining the future blood glucose value. In that regard, the Examiner's attention is directed to column 4 lines 26-29, where Worthington et al. teaches that its processor "determines the future blood glucose value $G(t_j)$ in

dependence upon the blood glucose value $G(t_d)$, the insulin dose value I_k, the insulin sensitivity value, and the insulin action value $F_k(t_d)$." One skilled in the art would readily appreciate that this processor is in direct contrast to the evaluation unit of claim 1 that uses the portion of insulin doses and that take effect within the desired interval as well as the portion of carbohydrates consumed that take effect during that interval to determine an extrapolated glucose concentration. As such, one skilled in the art, upon reading Worthington et al. would be led in a direction divergent from the path that the applicants took.

It is noted that Goldman et al. is devoid of description or suggestion of an evaluation unit formed for glucose concentration extrapolation, let alone a unit formed to use carbohydrates consumed in such an extrapolation. At most, Goldman et al. disclose (abstract) a health care system for specifying edibles to individual subjects, wherein the edibles include carbohydrates (column 6 lines 48-51). Conn et al. at disclose a monitoring system used for extracting small amounts of a target analyte from the biological system, and then sensing and/or quantifying the concentration of the target analyte. Neither of these references either alone or in combination with one another would lead one skilled in the art to modify Worthington et al. to meet the limitations of claim 1.

It is submitted that the teaching or suggestion, as well as the expectation of success, must come from the prior art and not applicant's disclosure. With this in mind it becomes apparent that Goldman et al. and Conn et al. when fairly considered for all that they teach, do not contain the requisite suggestion or incentive that would have motivated the skilled artisan to modify Worthington et al. to meet the limitations of claim 1, that being a system comprising "a data input device for entering insulin doses administered (I_i) and their times of administration (t_i), the same or a second data input device for entering carbohydrates (KH_j) consumed or to be consumed, and their times of consumption (t_j), a unit for determining the actual glucose concentration (G_a) in a patient's bodily fluid at a specific point in time (t_a), a memory unit for storing administered insulin doses and their times of administration, and carbohydrates consumed and their times of consumption, an evaluation device formed for evaluating the data stored in the memory unit and based upon that stored data, for extrapolating a glucose concentration at a point in time (t_p), whereby t_p is after t_a, and the extrapolation

comprises the following steps: determination of the portion (I_{wirk}) of insulin doses that take effect within the interval between t_a and t_p, determination of the portion (KH_{wirk}) of carbohydrates consumed that take effect in the interval between t_a and t_p, and determination of an extrapolated glucose concentration G_p at the point in time tp using I_{wirk} and KH_{wirk}."

It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Accordingly, reconsideration of the rejection of claims 1, 6-10, 36 and 37 leading to withdrawal of that rejection and allowance of the claims is requested.

The claims are believed to be in condition for allowance, and allowance of the application is respectfully requested. It is requested that this paper be considered a Petition for Extension of time sufficient to effect a timely response, and that all fees due be charged to Deposit Account Number 50-0877 with reference to (RDID 0006 US).

Respectfully submitted,
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